UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BARBARA GAYLE, *et al.*,	)	
	)	
Plaintiffs,	)	Case No. 1:19-CV-03451
	)	W.H.P. III, J.
v.	)	
	)	
PFIZER INC., *et al.*	)	
	)	
Defendants.	)	

PFIZER INC.'S MEMORANDUM IN SUPPORT OF MOTION FOR JUDGMENT ON THE PLEADINGS

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INTRODUCTION

The twenty-four Plaintiffs in this action allege that they or their spouses developed type-II diabetes by taking Lipitor, a prescription statin medication manufactured by Pfizer and approved by the FDA as safe and effective for reducing cholesterol and for the prevention of cardiovascular events in men and women. Plaintiffs allege that Pfizer failed to warn them that Lipitor allegedly increases the risk of developing diabetes, and that Lipitor is not effective for women. Plaintiffs' claims are virtually ***identical*** to claims brought by thousands of other plaintiffs that were consolidated and addressed in a Multidistrict Litigation ("MDL") before Judge Richard M. Gergel in the United States District Court for the District of South Carolina. Those claims were filed beginning in 2013 following the FDA's decision in 2012 to update the labeling for Lipitor and other statins to state that "[i]ncreases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including" Lipitor. In 2016, after substantial pretrial proceedings, the MDL court held that there was no admissible expert evidence that Lipitor was even capable of causing diabetes at three of its four available doses (10, 20, and 40 mgs), and that no plaintiff had produced any evidence that Lipitor caused her to develop diabetes. *See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 227 F. Supp. 3d 452, 491 (D.S.C. 2017); *In re Lipitor*, 226 F. Supp. 3d 557, 584 (D.S.C. 2017); *In re Lipitor*, 185 F. Supp. 3d 761, 770–71 (D.S.C. 2016). In 2017, the MDL court entered summary judgment for Pfizer as to all the plaintiffs in the MDL. In 2018, the Fourth Circuit unanimously affirmed the MDL court's rulings in their entirety. *See In re Lipitor*, 892 F.3d 624, 648 (4th Cir. 2018). And in April 2019, Plaintiffs filed this action. It should be dismissed for failure to state a claim.

At the outset, to the extent Plaintiffs' claims accrued after the 2012 label change, they are barred by federal preemption, which, as the Supreme Court recently held, presents a question of law suitable for resolution on a motion to dismiss. *Merck Sharp & Dohme Corp. v. Albrecht*, 139

S. Ct. 1668, 1686 (2019). To thread a viable path between alleged state-law duties to provide heightened warnings and the restrictions of the federal regulatory scheme on manufacturers' ability to change their labeling, a plaintiff must show that there was "newly acquired information," not previously submitted to the FDA, which would have warranted a heightened warning. Here, however, the FDA exhaustively reviewed the available evidence on this question in connection with the 2012 label change, and Plaintiffs do not even attempt to allege that any subsequent information exists that would warrant an additional warning. Their claims are thus preempted.

Moreover, not only are Plaintiffs' post-2012 claims preempted by federal law, but their pre-April 2016 claims are barred by the statute of limitations. Under New York's borrowing statute, Plaintiffs were required to file their claims at least within the period of limitations set by New York law, which runs three years from the date the plaintiff discovers her injury. CPLR 214-c. Here, since Plaintiffs filed in April 2019, any claims that accrued before April 2016 are time-barred. Nor can Plaintiffs avail themselves of the narrow exception for accrual based on the date of discovery of causation in CPLR 214-c(4). Among other things, that exception requires Plaintiffs to plead that scientific evidence did not exist to show causation, a contention that is belied by the fact that identical claims have been filed since 2013. And, in any event, even if this exception applied, the furthest back it could reach would be claims that accrued after April 2013, which would still be barred by preemption.

Finally, certain of Plaintiffs' claims fail for additional reasons. Their fraud claims have not been pled with the particularity required by Rule 9(b). Their express warranty claims are barred for failure to allege the express warranty at issue. And their consumer protection claims are barred by New York law. The Court should grant judgment on the pleadings dismissing Plaintiffs' Complaint with prejudice.

FACTUAL BACKGROUND

On April 15, 2019, Plaintiffs filed a Complaint in the New York Supreme Court for New York County, alleging fraud and personal injury claims. On April 18, 2019, Pfizer removed the action to this Court and filed its answer. Plaintiffs are twenty-four individuals residing in five states (Florida, Maine, Minnesota, Missouri, and Wyoming). (Compl. ¶ 2–25.)[1] Plaintiffs allege that each Plaintiff or Plaintiff's spouse was prescribed and ingested Lipitor for the treatment of high cholesterol and "diagnosed with type 2 diabetes while still taking" Lipitor. (Compl. ¶ 68.) Plaintiffs do not allege that Lipitor is defectively designed or that their particular medications were defectively manufactured. Instead, Plaintiffs allege that if they or their doctors had been aware of "problems concerning" some unidentified "risk of diabetes associated with Lipitor," (*id.* ¶ 69), Plaintiffs would not have been prescribed or taken the medication. Plaintiffs do not identify when or where they took Lipitor or the dates on which they were diagnosed with diabetes. Nor do they identify the extent of the alleged "risk" that they believe is "associated" with Lipitor, the basis for that belief, or any other supporting facts.

Lipitor is a branded form of atorvastatin calcium—a member of the statin class of mediations—manufactured by Pfizer and approved by the FDA as safe and effective for the prevention of cardiovascular disease and treatment of hyperlipidemia (high cholesterol) in both men and women. The FDA has never found a causal association between Lipitor and diabetes. As early as 2009, the FDA-approved labeling for Lipitor stated that, in the *Stroke Prevention by Aggressive Reduction in Cholesterol Levels* ("SPARCL") clinical trial, "[d]iabetes was reported

[1] Plaintiffs' counsel has stated that Plaintiff Michelle O'Bremski, who has been joined in a separate action in New York state court, will be voluntarily dismissed from this action, (ECF No. 17), but has not yet filed the papers to do so.

as an adverse reaction in 144 subjects (6.1%) in the [80mg] atorvastatin group and 89 subjects (3.8%) in the placebo group." (Ex. A, 2009 Lipitor Packaging Insert § 6.1.)[2]

In February 2012, after consulting with statin manufacturers and other constituents in the medical field and reviewing the relevant clinical trials and medical literature—including literature investigating whether statin medications are associated with diabetes—the FDA issued a drug safety announcement directed at doctors and patients, concluding that the FDA "continues to believe that the cardiovascular benefits of statins outweigh these small increased risks." (Ex. B, *FDA Drug Safety Communication: Important Safety Label Changes to Cholesterol-Lowering Statin Drugs* (Feb. 28, 2012).)

The 2012 drug safety announcement was accompanied by a change to the labeling of several statins, including Lipitor. Significantly, although "information concerning an effect of statins on incident diabetes and increases in HbA1c and/or fasting plasma glucose was added to statin labels," the FDA chose not to include diabetes in the "Warnings and Precautions" section of

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[2] The Court may consider, at the motion-to-dismiss stage, the FDA's communications with statin manufacturers, its public announcements, and Lipitor's FDA-approved labeling. The communications and labeling are explicitly referenced in Plaintiffs' Complaint and form the basis of Plaintiffs' claims. (Compl. ¶¶ 46–49); *see also, e.g.*, *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1378 n.5 (Fed. Cir. 2012); *Gerritsen v. Warner Bros. Entm't Inc.*, 116 F. Supp. 3d 1104, 1118–19 (C.D. Cal. 2015); *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 653 (S.D. Tex. 2010); *Berman v. Sugo LLC*, 580 F. Supp. 2d 191, 200 (S.D.N.Y. 2008); *In re Worldcom, Inc. Sec. Litig.*, 294 F. Supp. 2d 392, 406 (S.D.N.Y. 2003). Moreover, the labeling and public announcements are judicially noticeable public documents the authenticity and contents of which are not reasonably subject to dispute. *See In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Ltiig.*, 333 F. Supp. 3d 135, 152 (E.D.N.Y. 2018) (taking judicial notice of FDA documents that "are referenced in the complaints and publicly available from sources whose accuracy cannot reasonably be questioned"); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 481 n.26 (W.D. Pa. 2012) (taking judicial notice of Summary of Safety and Effectiveness Data of medical device); *Lewkut*, 724 F. Supp. 2d at 653 (S.D.N.Y. 2010) ("PMP approval and FDA documents describing the Trident System are matters of public records . . . ."); *Trisvan v. Heyman*, 305 F. Supp. 3d 381, 400 (E.D.N.Y. 2018) (collecting cases taking judicial notice of FDA-approved labeling); *see also Coleman v. Supreme Court*, 697 F. Supp. 2d 493, 514 (S.D.N.Y. 2010) (taking judicial notice of "associated" side effects listed in the Physicians' Desk Reference).

labeling for statins (including the labeling for Lipitor), and did not conclude that statins are capable of ***causing*** diabetes. Instead, the FDA kept the existing description of the SPARCL trial in the "Adverse Reactions" section of the Lipitor labeling, and updated the labeling to list hyperglycemia (a defining characteristic of diabetes) as a potential adverse reaction and to warn (in the "Warnings and Precautions" section) that "[i]ncreases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including" Lipitor. (Ex. C, Lipitor Packaging Insert §§ 5.3, 6.1.)

In January 2014, the FDA issued a public consumer health statement on statin medications relating to various "concerns," such as potential confusion and muscle damage. (Ex. D, *FDA Expands Advice on Statin Risks* (Jan. 2014).) And although the FDA again noted that some statin clinical trials had "reported" diabetes as an adverse event, it did not make ***any*** additional labeling changes relating to diabetes or hyperglycemia. Instead, the FDA advised doctors and patients in the public statement "that blood-sugar levels may need to be assessed after instituting statin therapy," and stated that it "will be changing the drug labels of popular statin mediations to reflect" some of the ***other*** topics discussed in the consumer health statement. (*Id.*)

LEGAL STANDARD

"Motions under Rule 12(c) are considered under the same standard as that applicable to motions to dismiss under Rule 12(b)(6)." *Multimedia Plus, Inc. v. Playerlync, LLC*, 198 F. Supp. 3d 264, 267 (S.D.N.Y. 2016) (Pauley, J.), *aff'd*, 695 F. App'x 577 (Fed. Cir. 2017). "To withstand dismissal, a pleading 'must contain sufficient factual matter . . . to state a claim to relief that is plausible on its face.'" *Ambac Assurance Corp. v. U.S. Bank Nat'l Assoc.*, 328 F. Supp. 3d 141, 155 (S.D.N.Y. 2018) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) (internal quotation mark omitted)). "[A] plaintiff must plead 'factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Id.* "Although the plausibility

standard is 'not akin to a "probability requirement," . . . it asks for more than a sheer possibility that a defendant has acted unlawfully.'" *Id.* Additionally, under Rule 9(b), claims sounding in fraud must be pleaded with particularity. FED. R. CIV. P. 9(b). Plaintiffs "must '(1) specify the statements that [they] contend[] were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.'" *Tears v. Boston Sci. Corp.*, 344 F. Supp. 3d 500, 514 (S.D.N.Y. 2018) (quoting *Nakahata v. New York-Presbyterian Healthcare Sys., Inc.*, 723 F.3d 192 (2d Cir. 2013)).

ARGUMENT

I. THE 2012 LABEL CHANGE BARS PLAINTIFFS' CLAIMS

The FDA's 2012 decision to change the Lipitor label to warn of reports of hyperglycemia poses a fatal dilemma to Plaintiffs' claims. On one side, if Plaintiffs developed diabetes ***after*** that label change, they face preemption: to survive preemption, Plaintiffs must, at a minimum, plead the existence of newly acquired information not considered by the FDA that would have warranted a stronger warning that would have caused their doctors not to prescribe Lipitor. Plaintiffs have failed to do so. But on the other side, if they developed diabetes ***before*** that label change—or, in fact, any time before April 2016—their claims are barred by the three-year statute of limitations. Under either scenario, Plaintiffs' claims fail as a matter of law and should be dismissed.

A. Plaintiffs' Post-2012 Claims Are Preempted

Whether a state-law failure-to-warn claim against a manufacturer of a branded prescription medication is preempted is a question of law that may be resolved by the Court at the pleading stage. *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019); *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 42–43 (1st Cir. 2015); *Utts v. Bristol-Myer Squibb Co.*, 251 F. Supp. 3d 644, 372 (S.D.N.Y. 2017). To resolve that question, the Court must decide whether "federal law (including appropriate FDA actions) prohibited [Pfizer] from adding

any and all warnings to the drug label [for Lipitor] that would satisfy state law." *Merck*, 139 S. Ct. at 1678; *accord Wyeth v. Levine*, 555 U.S. 555, 571 (2009); *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488–89 (2013); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613–15 (2011). Here, under recent authority from the Supreme Court and the Second Circuit, that impossibility is apparent from the face of Plaintiffs' Complaint because they identify no facts showing that Pfizer could have changed the labeling for Lipitor to include heightened warnings on type 2 diabetes. *Merck*, 139 S. Ct. at 1678; *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699 (2d Cir. 2019).

As set forth above, the factual basis of Plaintiffs' state-law claims is a failure-to-warn theory. "To prevail on [a] failure-to-warn claim," Plaintiffs "must demonstrate both that [Pfizer] failed to provide an adequate warning 'of dangers inherent in the use'" of Lipitor, "and that the omission was the proximate cause of [their] injuries." *Dean v. Eli Lilly & Co.*, 387 F. App'x 28, 30 n.3 (2d Cir. 2010). Under the state-law learned intermediary doctrine, the manufacturer's duty to warn of the risks of a prescription medication runs not to the patient, but to the prescribing physician through the product labeling.[3]

Although Pfizer maintains, consistent with the MDL and Fourth Circuit rulings, that there is no reliable scientific evidence that Lipitor causes diabetes, Plaintiffs' failure-to-warn claims would be preempted even if they ***could*** prove medical causation.[4] As the Supreme Court's recent

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[3] *Rohde v. Smiths Med.*, 165 P.3d 433, 436 (Wyo. 2007); *Tardy v. Eli Lily & Co.*, No. CV-03-538, 2004 WL 1925536, at *3 (Me. Super. Ct. Aug. 3. 2004); *Buckner v. Allergan Pharm., Inc.*, 400 So.2d 820, 822 (Fla. D. Ct. App. 1981); *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 885 (Minn. 1970); *Johnston v. Upjohn Co.*, 442 S.W.2d 93, 95 (Mo. 1969). Pfizer assumes, for the sake of this Motion only, that the laws of Plaintiffs' home states apply.

[4] As the MDL court and the Fourth Circuit held, there is no evidence that the most common doses of Lipitor are even associated with, let alone capable of causing, diabetes. Indeed, diabetes is a complex disorder that develops over many years, and whatever "association" might exist is not a ***causal*** association at any dose. But in any event, Plaintiffs have not pleaded a failure-to-warn claim: any doctor prescribing Lipitor after February 2012 would have been aware of whatever "association" exists between diabetes, statins generally, and Lipitor specifically, based

decision in *Merck* shows, even assuming that state law imposes a duty to give a different warning, that duty may impermissibly conflict with the federal regulatory scheme, which strictly limits the circumstances and manner in which a manufacturer may provide a different warning in its labeling. The Food Drug & Cosmetic Act charges the FDA "with ensuring that prescription drugs are 'safe for use under the conditions prescribed, recommended, or suggested' in the drug's 'labeling.'" *Merck*, 139 S. Ct. at 1672 (quoting 21 U.S.C. § 355(d)).[5] "When the FDA exercises this authority, it makes careful judgments about what warnings should appear on a drug's label for the safety of consumers." *Id.*; *see also* 21 U.S.C. § 393(b)(2)(B). "To obtain FDA approval, drug companies generally must submit evidence from clinical trials and other testing that evaluate the drug's risks and benefits and demonstrate that it is safe and effective for all of the indications 'prescribed, recommended, or suggested' on the drug's label." *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 239 (3d Cir. 2012) (quoting 21 U.S.C. § 355(d)).

Because "the FDA retains authority to reject labeling changes," a manufacturer cannot be held liable where "the FDA would not have approved a change to" the medication's labeling or marketing materials to add the warnings or safety information that a plaintiff's claims would require. *Wyeth v. Levine*, 555 U.S. 555, 571 (2009); *accord Mut. Pharm. Co. v. Bartlett*, 570 U.S.

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on: (1) the nationwide MDL involving the exact same claims alleged here; (2) the FDA-approved labeling for Lipitor; and (3) public submissions to and announcements by the FDA.

[5] "Labeling" includes not only packaging inserts, but "virtually all communication with medical professionals" about a medication. *Del Valle v. PLIVA, Inc.*, 2011 WL 7168620, at *4 (S.D. Tex. Dec. 21, 2011), *report and rec. adopted sub nom. Del Valle v. Qualitest Pharm. Inc.*, 2012 WL 2899406 (S.D. Tex. June 22, 2012), *aff'd sub nom. Lashley v. Pfizer, Inc.*, 750 F.3d 470 (5th Cir. 2014); *see also, e.g.*, 21 C.F.R. §§ 202.1(l)(2), 314.81; *Strayhorn v. Wyeth Pharma., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013); *cf. Newman v. McNeil Consumer Healthcare*, No. 10-1541, 2013 WL 7217197, at *5 (N.D. Ill. Mar. 29, 2013); *DePriest v. AstraZeneca Pharm., L.P.*, 351 S.W.3d 168, 177–78 (Ark. 2009); *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1234–35 (S.D. Fla. 2007).

472, 488–89 (2013); *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1105 (10th Cir. 2017).[6] To include a warning or adverse reaction in a medication's labeling, there must be "reasonable evidence of a causal association with a drug." 21 C.F.R. § 201.57(6)(i). In fact, the FDA frequently chooses not to include warnings and adverse reactions that are not supported by sufficient evidence because it does not want to "discourage use of beneficial medications." *Cerveny*, 855 F.3d at 1102.

Because the FDA's default is to require prior approval of each label change, a state-law claim alleging that a different warning should have been issued is preempted unless the plaintiff shows that a unilateral label change would have been permitted.[7] A manufacturer can make a unilateral change to add warnings to a label only through the FDA's "Changes Being Effected" or "CBE" process to address "newly acquired information." 21 C.F.R. § 314.70(c)(6)(iii). And "[n]ewly acquired information" is a narrow term defined by regulation as "data, analyses, or other information ***not previously submitted to the [FDA]*** . . . if the studies, events, or analyses reveal risks of a ***different type or greater severity or frequency than previously included in submissions to FDA***." *Id.* § 314.3(b) (emphases added). Additionally, the CBE must "satisf[y] the standard

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[6] *See also, e.g.*, *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613–15 (2011); *Cerveny v. Aventis, Inc,* No. 17-4204, 2019 WL 3763441, at *3 n.9 (10th Cir. Aug. 9, 2019); *Guilbeau v. Pfizer, Inc.*, 880 F.3d 304, 317 (7th Cir. 2018); *Rheinfrank v. Abbott Labs., Inc.*, 680 F. App'x 369, 385 (6th Cir. 2017); *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 42–43 (1st Cir. 2015); *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 662–63 (S.D.N.Y. 2017); *Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1173–74 (S.D. Cal. 2016); *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1276–77 (W.D. Okla. 2011).

[7] The prior-approval process preempts state-law failure-to-warn claims because the manufacturer would be forbidden from providing the allegedly necessary warnings until ***after*** the FDA makes its decision, which often takes years. Accordingly, courts universally apply the CBE-regulation's newly-acquired-information requirement as the standard for determining whether a warning claim is preempted. *See, e.g.*, *Merck*, 139 S. Ct. at 1677 (describing the role the CBE regulations played in the *Wyeth* decision); *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708 (2d Cir. 2019) (applying CBE regulations in holding that warning claim is preempted); *In re Lipitor*, 185 F. Supp. 3d 761, 769–70 (D.S.C. 2016) (applying the CBE regulation in determining that efficacy claims were preempted).

for inclusion in the labeling"—*i.e.*, there must be reasonable evidence of a causal association—and is subject to the FDA's subsequent approval or rejection. *Id.* § 314.70(c)(6)(iii), (7). In sum, "manufacturers cannot propose a change that is not based on reasonable evidence," *Merck*, 139 S. Ct. at 1677, and "any claim that a drug label should be changed based on information previously submitted to the FDA is preempted because the CBE regulation cannot be used to make a label change based on such information." *In re Lipitor*, 185 F. Supp. 3d 761, 769–70 (D.S.C. 2016).

Plaintiffs here do not get past the first step. Plaintiffs acknowledge that the 2012 labeling change was the result of "the FDA's comprehensive review [of] clinical trial data" (Compl. ¶ 46), which resulted in a new warning that the FDA determined was warranted based on the available information: "[i]ncreases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including" Lipitor. (Ex. C § 5.3.) The FDA further noted that in the SPARCL clinical trial, "[d]iabetes was reported as an adverse reaction in 144 subjects (6.1%) in the [80mg] atorvastatin group and 89 subjects (3.8%) in the placebo group." (*Id.* § 6.1.) If the FDA believed that there was reasonable evidence of a causal association between Lipitor and diabetes, it would have included a warning to that effect in the labeling. The FDA found no such association.

Nor have Plaintiffs identified any newly acquired information, let alone information that satisfies the FDA's stringent CBE requirements. The Second Circuit's decision earlier this year in *Gibbons* is directly on point. There, the plaintiffs alleged "that 'before and after marketing Eliquis, Defendants became aware of many reports of serious hemorrhaging in users of their drugs'" and that "'numerous . . . studies published after Eliquis' approval in 2012 confirm the problematic bleeding events associated with Eliquis.'" 919 F.3d at 708 (internal quotations and alterations omitted). Although the plaintiffs attached "reports, studies, and articles" to their

complaints, the court nonetheless affirmed the dismissal of the failure-to-warn claims on preemption grounds. *Id.* The court explained that the complaints "consist[ed] of 'conclusory and vague' allegations and d[id] not plausibly allege the existence of newly acquired information that could have justified Defendants' revising the Eliquis label through the CBE regulation"—specifically, the plaintiffs "provide[d] no basis upon which the court could conclude that the bleeding events covered by the alleged 'reports' and 'studies' presented ***a different type of risk than those the company had discussed with the FDA, or were more severe or more frequent than bleeding events that the government already knew about***." *Id.* (emphasis added).

Here also, Plaintiffs offer no factual allegations whatsoever that plausibly demonstrate the existence of newly acquired information showing that Lipitor is associated with any "risks" that are different or more serious than the information already considered by the FDA and already described in the labeling, much less identify "reports, studies, and articles" that have not been submitted to the FDA. *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 42–43 (1st Cir. 2015) (dismissing claims as preempted where plaintiffs challenged Lexapro's FDA-approved labeling but did not allege that the information on which their claims relied "was unknown to the FDA prior to label approval"); *Utts v. Bristol-Myer Squibb Co.*, 251 F. Supp. 3d 644, 369 (S.D.N.Y. 2017) (dismissing claims as preempted because plaintiffs did not identify newly acquired information in their complaint).[8] As a result, Plaintiffs' post-2012 claims are preempted as a matter of law and should be dismissed.

[8] To the extent that Plaintiffs are allege or imply that Pfizer concealed any studies from the FDA, such allegations are also preempted. *See Buckman Co. v Pls.' Legal Comm.*, 531 U.S. 341, 353 (2001).

B. Plaintiffs' Pre-2016 Claims Are Time-Barred

Not only are any claims that accrued after 2012 preempted, but any claims that accrued before April 2016 are barred by the statute of limitations. Under New York's borrowing statute, courts in New York (including this Court) apply the shorter of New York's statute or the state-of-injury's statute of limitations. CPLR 202. Because a longer statute of limitations cannot apply under the borrowing statute and Plaintiffs have not pleaded facts showing their place of injury, Pfizer analyzes the timeliness of Plaintiffs' claims under New York law for the purpose of this Motion.

New York's personal injury statute of limitations generally requires filing of claims within three years of the date on which the claim accrues. *Id.* 214(5); *see also Trisvan v. Heyman*, 305 F. Supp. 3d 381, 397 (E.D.N.Y. 2018) (applying three-year limitations period to fraud claims that were incidental to personal injury claims). Although that accrual is subject to a discovery rule, "it is 'discovery of the injury, not discovery of the other elements of a claim,' that 'starts the clock.'" *Levy v. BASF Metals Ltd.*, 917 F.3d 106, 108 (2d Cir. 2019) (quoting *Rotella v. Wood*, 528 U.S. 549 (2000)); *see also* CPLR 214-c(2). Accordingly, to the extent that any particular Plaintiff or his or her spouse experienced or was diagnosed with diabetes before April 2016, that Plaintiff's claims are time-barred. *Compare Pompa v. Burroughs Wellcome Co.*, 696 N.Y.S.2d 587, 590 (3d Dep't 1999) ("Under CPLR 214–c, discovery of an ***injury*** occurs 'when the injured party discovers the primary condition on which the claim is based' . . . which may include being actually diagnosed as suffering from a particular disease." (citations omitted) (quoting *In re N.Y. Cty. DES Litig.*, 678 N.Y.2d 506 (1997))), *with Galletta v. Stryker Corp.*, 283 F. Supp. 2d 914, 917 (S.D.N.Y. 2003) (holding that limitations period began to run when plaintiff began experiencing symptoms, before the cause of those symptoms was actually diagnosed). As a result, any Plaintiff who began

experiencing his or her alleged injury or was diagnosed with diabetes more than three years before the filing of this action—that is, April 2016—is time-barred.

Nor can Plaintiffs save their claims under the limited exception to this rule, which provides that, "where the discovery of the cause of the injury is alleged to have occurred less than five years after discovery of the injury," a plaintiff may bring a claim "within one year of such discovery of the cause of the injury." CPLR 214-c(4). Initially, the earliest injury on which this exception would conceivably permit suit would be six years prior to filing of the action—here, April 2013—and such claims would still be preempted. (*See* Part I.A, *supra*.) But, in any event, Plaintiffs cannot invoke this exception, which requires them "***to allege and prove*** that technical, scientific or medical knowledge and information sufficient to ascertain the cause of [her] injury had not been discovered, identified or determined prior to the expiration of the" initial three-year period. CPLR 214-c(4) (emphasis added). Not only do Plaintiffs fail to make this allegation, but the allegation is also undermined by the 2012 label change: it is a matter of public record that the FDA warned of increases in HbA1c in 2012, and that subsequently thousands of lawsuits were filed in state and federal courts around the country—including other lawsuits by Plaintiffs' counsel—alleging claims indistinguishable from those that Plaintiffs advance here. *See generally In re Lipitor*, 892 F.3d 624, 648 (4th Cir. 2018). In light of that label change, any conclusory allegation "that technical, scientific or medical knowledge" was insufficient to give Plaintiffs notice of their claims by the expiration of the initial period—here, April 2016, at the very latest—is implausible and need not be credited by the Court.

Finally, Plaintiffs cannot avoid a statute of limitations bar through their conclusory allegation that "Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiffs and their physicians the true risks associated with the use of Lipitor."

(Compl. ¶ 83.) Plaintiffs bear the burden of establishing fraudulent concealment. *Rio Tinto PLC v. Vale*, No. 14-3042, 2015 WL 7769534, at *8 (S.D.N.Y. Nov. 20, 2015). As this Court has held, fraudulent concealment requires a plaintiff to plead "***with particularity*** (1) wrongful concealment by the defendant; (2) which prevented the plaintiff's discovery of the nature of the claim within the limitations period; and (3) due diligence in pursuing discovery of the claim." *In re Crude Oil Commodity Futures Litig.*, 913 F. Supp. 2d 41, 59 (S.D.N.Y. 2012) (Pauley, J.) (emphasis added). As explained below (*see* Part II.A, *infra*), Plaintiffs have failed to allege fraud with the particularity required by Rule 9(b). Nor have they alleged facts showing their "due diligence in pursuing discovery of the[ir] claim[s]." *In re Crude Oil Commodity Futures Litig.*, 913 F. Supp. 2d at 59. Because Plaintiffs' claims are substantively ***identical*** to the widely publicized (albeit false) allegations made by thousands of other plaintiffs around the country dating back to 2013, Plaintiffs have not alleged (and cannot allege) facts showing that they acted with diligence to discover but could not discover their claims before April 2016. The Lipitor MDL was not a secret; and as this Court has previously held in similar circumstances, Plaintiffs cannot plausibly allege that they could not have uncovered, through reasonable diligence, an alleged "association" that was widely publicized and subjected to intense public scrutiny.[9] In sum, Plaintiffs have not alleged any basis

[9] *See Youngers v. Virtus Inv. Partners Inc.*, 195 F. Supp. 3d 499, 521 (S.D.N.Y. 2016) (Pauley, J.) (dismissing claims as time barred where "multiple news reports published in December 2013 detail the exact wrongs alleged in the Complaint and 'would have led a reasonably diligent plaintiff to have discovered the facts underlying his claim'" (quoting *In re Magnum Hunter Res. Corp. Sec. Litig.*, 616 F. App'x 442 (2d Cir. 2015))); *Pa. Pub. Sch. Emp. Ret. Sys. v. Bank of America Corp.*, 874 F. Supp. 2d 341 (S.D.N.Y. 2012) (Pauley, J.) (holding that Securities Act claims were time barred where "news articles, SEC filings, and various lawsuits . . . demonstrate[d] that a reasonably diligent plaintiff would have discovered the facts constituting the violation"); *see also Ridenour v. Boehringer Ingelheim Pham., Inc.*, 679 F.3d 1062, 1066 (8th Cir. 2012) ("A reasonable inquiry by Ridenour in late 2007 would have resulted in him learning of a body of scientific research regarding a potential link between Mirapex and compulsive behaviors, as well as a significant number of lawsuits regarding the same.").

for tolling the statutory period, and to the extent that any Plaintiff was diagnosed with diabetes before April 2016, her claims are time barred as a matter of law.

II. PLAINTIFFS' CLAIMS FAIL FOR ADDITIONAL REASONS

A. Plaintiffs Have Failed to Plead Fraud with Particularity

Plaintiffs' fraud, fraudulent concealment, and negligent misrepresentation claims must be pleaded with particularity under Rule 9(b), and therefore Plaintiffs must identify the allegedly fraudulent statements or omissions, why they were fraudulent, and the circumstances in which they occurred. *See Tears v. Boston Sci. Corp.*, 344 F. Supp. 3d 500, 514–16 (S.D.N.Y. 2018). Plaintiffs' Complaint is filled with boilerplate allegations without any factual support. Plaintiffs vaguely assert that Defendants "over-promoted" Lipitor and made "statements, representations and advertisements" that "were deceptive, false, incomplete, misleading and untrue" (Compl. ¶¶ 60, 78), but do not identify ***any*** specific statements or omissions by Defendants or their agents, let alone the particular statements or omissions on which Plaintiffs or their prescribing doctors allegedly relied, when those statements were made, and why they were fraudulent. Although Plaintiffs vaguely allege that Defendants failed to disclose unidentified "studies" showing "problems concerning" some unspecified "risk [of] diabetes associated with Lipitor" *(id.* ¶ 69), they do not identify the specific information that was omitted or why that omission made Lipitor's labeling fraudulent.[10] Plaintiffs thus have not identified the who, what, when, and how required by Rule 9(b). Accordingly, the Court should dismiss Plaintiffs' claims that sound in fraud, including Counts II, V, and VI, for failing to plead with particularity.

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[10] In fact, Plaintiffs do not attempt to describe, ***in even general terms***, the extent of that "risk," or identify the basis of their (false) allegations such that Pfizer could attempt to determine the "risk" to which they are referring. As explained above (*see* Part I.A, *supra*, at n.5), Plaintiffs' failure to allege how that alleged "risk" conflicts with the studies explicitly discussed in Lipitor's labeling and the FDA's related drug-safety announcements is fatal to Plaintiffs' failure-to-warn claims as well.

B. Plaintiffs Have Failed to Plead a Breach of Warranty Claim

Plaintiffs' warranty claims fail because they must, but do not, identify the relevant statement constituting the warranty. *E.g.*, *Quintana v. B. Braun Med. Inc.*, No. 17-6614, 2018 WL 3559091, at *6 (S.D.N.Y. July 24, 2018); *in re Bisphenol-A (BPA) Polycarbonate Plastic Prods. Liab. Litig.*, 687 F. Supp. 2d 897, 905 (W.D. Mo. 2009). As explained above (*see* Part II.A, *supra*), Plaintiffs have not identified any affirmative statements by Pfizer. In addition, Florida, Minnesota, and Wyoming do not recognize breach of implied warranty claims in prescription-medication personal-injury actions. *See, e.g., Timmons v. Purdue Pharma Co.*, No. 8:04-CV-1479-T-26MAP, 2006 WL 263602, at *5 (M.D. Fla. Feb. 2, 2006); *Barrow v. Bristol-Myers Squibb Co.*, No. 96-689-CIV-ORL-19B, 1998 WL 812318, at *46 (M.D. Fla. Oct. 29, 1988); *In re Shigellosis Litig.*, 647 N.W.2d 1, 11–12 (Minn. Ct. App. 2002) (implied warranty claims are preempted by strict liability statute); *see also Jacobs v. Dista Prods. Co.*, 693 F. Supp. 1029, 1036 (D. Wyo. 1988) (holding that implied-warranty claims must be dismissed if failure-to-warn claims are dismissed). Accordingly, this provides additional grounds for the Court to dismiss Count III (express warranty) as to all Plaintiffs, and to dismiss Count IV (implied warranty), except as to Plaintiffs Sharron Stewart, Shenna Albert, and Carletha Foster.

C. Plaintiffs Have Failed to Plead a Consumer Protection Claim

Although Plaintiffs' claims under General Business Law §§ 349 and 350 ("NYCPA") are based on the same defective failure-to-warn theory as their common law claims, their NYCPA claims fail for several additional reasons. "To state a claim for deceptive trade practices under this section, a plaintiff must establish that: (1) the defendant engaged in an act that was directed at consumers; (2) the act engaged in was materially deceptive or misleading; and (3) the plaintiff was injured as a result of the defendant's act." *Amos v. Biogen Idec Inc.*, 28 F. Supp. 3d 164, 173 (W.D.N.Y. 2014).

First, "because a drug manufacturer's duty to warn of a drug's side effects runs to the doctor prescribing the drug, and not to the user of the drug, the issuance of drug warnings, for purposes of Section 349, is not an act directed at consumers." *Id.* Accordingly, "courts construing the [NYCPA] have held that" it does "not apply to claims involving prescription drugs." *Aston v. Johnson & Johnson*, 248 F. Supp. 3d 43, 57 (D.D.C. 2017). Count VII thus fails as a matter of law and must be dismissed.

Second, in alleging an NYFCA claim, "[a] pleading is insufficient if it does not include facts illustrati[ng] 'a causal connection between some injury to plaintiffs and some misrepresentation made by defendants.'" *Tears v. Boston Sci. Corp.*, 344 F. Supp. 3d 500, 516 (S.D.N.Y. 2018) (quoting *Small v. Lorillard Tobacco Co.*, 679 N.Y.S.2d 593 (App. Div. 1st Dep't 1998)). Moreover, to plead a deceptive advertising claim under § 350, a plaintiff must allege that she actually saw the advertisement before purchasing the product. *Gale v. Int'l Bus. Mach. Corp.*, 781 N.Y.S.2d 45, 47 (App. Div. 2d Dep't 2004). As explained above (*see* Part II.A, *supra*), Plaintiffs have not identified any misrepresentations made by Pfizer, let alone alleged that they saw those representations and suffered resulting harm. Accordingly, the Court should dismiss Count VII to the extent that it relies on advertising or affirmative misrepresentations.

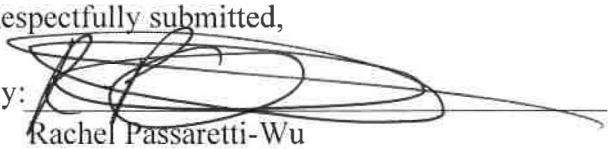
Third, Plaintiffs' claims are barred by the NYCPA's safe harbor provision, under which it is a "complete defense that act or practice" complained of by the plaintiff is "subject to and complies with the rules and regulations of, and the statutes administered by . . . any official department, division, commission or agency of the United States." N.Y. GEN. BUS. § 349(d). Because Plaintiffs' claims would impermissibly require Pfizer to change the labeling for Lipitor contrary to the FDA's determinations, Count VII is not only preempted (*see* Part I.A, *supra*), but also barred by the safe harbor provision.

CONCLUSION

For the foregoing reasons, the Court should grant judgment on the pleadings dismissing Plaintiffs' Complaint with prejudice in its entirety.

Dated: New York, New York.
September 16, 2019

Respectfully submitted,

By: 

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CERTIFICATE OF SERVICE

I hereby certify that on September 16, 2018, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which sends electronic notification of such filing to all CM/ECF participants.

/s/ Rachel Passaretti-Wu
Rachel Passaretti-Wu